Cormorant. Policy Advice

4 August 2017

The Secretary
Senate Community Affairs Legislation Committee
Parliament House
CANBERRA ACT 2600

Dear Secretary,

VAPORISED NICOTINE PRODUCTS BILL 2017

This is a submission commenting on the Private Senator's Bill introduced by Senators Leyonhjelm and Roberts, and referred to the Committee for consideration.

This submission generally will not comment on policy and regulation reform in respect of vaporised nicotine products, also known as Electronic Nicotine Delivery Systems (ENDS). I have made a policy-based submission to the concurrent inquiry on ENDS policy and regulation being undertaken by the House of Representative Standing Committee on Health, Ageing and Sport, and that submission is available to this Committee, as are the hundreds of other publicly-available submissions made to that inquiry.

It will not comment on the science, other to presume the evidence in favour of ENDS and vaping, and for smokeless tobacco products like Swedish snus, is positive and increasingly definitive respecting the low relative risk of these products to smoking combustible tobacco.

Rather, it is intended to complement evidence in submissions made by people and organisations expert in the science and technology of tobacco harm reduction, including vaping. The suggestions here are made from the perspective of applying prudent public policy, with the intention of removing smokers from the morbidity and mortality risks of smoking using every means available, including new and disruptive technologies.

I have had over twenty years' experiences working in health and social policy and regulation, including as a senior adviser to two Commonwealth Health ministers. Further details of my background are at Attachment A.

GENERAL COMMENTS ON THE BILL

This Bill will not pass its Second Reading unless the Government supports it.

That is unlikely given the inquiry in progress in the House of Representatives, which has terms of reference given to it by the Minister for Health, Ageing and Sport. This submission assumes the Government will not act on liberalising the regulation of ENDS, if at all, until it has considered the recommendations of the Lower House inquiry.

Nevertheless, this Bill is timely and important. It provides a potential template for model legislation that could be implemented if the Government accepts that vaporised nicotine products, known as "vaping", and smokeless tobacco products such as snus, are cleared for legal use in Australia.

If there is a model Bill ready to go thanks to this Senate process, the chances of rapid legalisation of nicotine delivery other than by smoking combustible tobacco, with all the deadly components of that smoke, are all the greater.

As I argue in my submission to the House of Representatives inquiry, that would be good public policy and that an appropriate application of the precautionary principle – that keeping people away from worse harm – would permit legal access to ENDS and smokeless tobacco, not prevent it as it is being applied now.

COVERAGE OF THE BILL

This submission concentrates on the content of this Bill, and will address, briefly, the three areas of proposed amendments in the Bill's Schedule 1: the *Therapeutic Goods Act 1989*; the *Airports Act 1996*; and the *Tobacco Advertising Prohibition Act 1992*.

Submission by Mr Clive Bates

I have seen the submission by Mr Bates of the United Kingdom. Mr Bates is a world-recognised authority on tobacco harm reduction, a powerful anti-smoking advocate, and has extensive experience in tobacco control, including as a former director of Action on Smoking and Health UK.

Mr Bates's submission is a detailed, constructive and measured forensic analysis by a highly-respected international expert. It highlights the strengths and weaknesses of the coverage of this Bill, and I generally endorse his conclusions and recommendations to improve this Bill.

Nevertheless, as an Australian health and social policy analyst and practitioner, I will make my own comments that may assist the Committee.

The Bill as an *ad hoc* policy application

As I said in my submission to the House of Representatives inquiry, I have difficulty with Bills of this nature. They are *ad hoc* measures to fix specific policy problems and, grafted to existing policy and legislation, they can stick out like a sore thumb.

This Bill was drafted after a detailed scientific application was submitted to the Therapeutic Goods Administration (TGA) to amend the listing of nicotine on Schedule 7 of the Poisons Standard. That application was rejected by the TGA on tenuous public policy and ideological grounds rather than the intrinsic scientific merit of the application, and detailed scientific reasons for the rejection were not given.

The consultation and decision processes applied by the TGA including the needlessly heavy redaction of submissions received during the consultation phase of the application, indicate internal biases in the TGA and the Department of Health against new ENDS technologies.

This failed application indicates procedural and administrative flaws in the TGA scheduling review regime, not just in relation to the treatment of nicotine. It indicates there is a wider policy problem to be fixed, particularly in relation to the impartial, publicly-transparent and scientifically-defensible administration of listing and scheduling applications under the TGA.

A normal policy approach would start with an independent external review of the operation of TGA listing and scheduling processes in general, and consider any legislative fixes across the operation of the whole system, in the interests of consistency and fairness.

Nevertheless, there is a specific and seemingly intractable problem relating to ENDS and smokeless tobacco, particularly in the mindset of officials and advisers who refuse to consider on the weight of emerging scientific merits the value of ENDS as tobacco harm reduction, to the point that no consideration, let alone acceptance, of their merit and potential is remotely possible without specific legislative intervention.

That seems to be the conclusion reached by Senators Leyonhjelm and Roberts. If the intent of this Bill is to cut through unsubstantiated resistance to change by specific legislation, because there is no other way that TGA and related processes will consider ENDS other than reject them, then there is some justification to an *ad hoc* Bill for this specific purpose, however distasteful from a policy-making perspective.

This Bill is a last-resort intervention. Considering it favourably must not assume *ad hoc* approaches of this nature should become normal, first-resort solutions to intractable public policy impasses.

With reference to the above comments, the intent of the Senators in drafting the proposed amendments to this Act in the Bill is supported, with reservations.

Therapeutic Goods Act 1989

The Bill, if enacted, certainly would remove the absurdity in the current scheduling of nicotine under the Poisons Standard is only generally – and ridiculously – available only in "tobacco prepared and packed for smoking": in other words, combustible cigarettes, pipes and other methods of consuming tobacco smoke.

As is becoming clear from emerging and reliable scientific evidence, as submissions to this and the House of Representative inquiry will have outlined, vaping and smokeless tobacco consumption is almost certainly of minimal to negligible health risk compared to combustible tobacco smoking. The UK Royal College of Physicians and Public Health England have both concluded the risk is "at least" 95 per cent less than combustible tobacco smoking, yet cigarettes are legal in Australia and ENDS using nicotine are not.

My view is that the provisions of this Bill relating to the *Therapeutic Goods Act* address this glaring and embarrassing public health anomaly adequately, but incompletely.

The Bill's provisions, as drafted, could be amended in four ways in relation to this Act:

- Not prescribe a nicotine concentration in ENDS liquids. This is better left to the Minister for Health prescribing an appropriate content level by regulation, based on expert scientific advice and international best practice about the appropriate concentration, which could be amended up or down as the body of scientific evidence becomes more comprehensive and definitive;

- The terms of scheduling nicotine stipulate compliance with minimum product standards for e-liquids and their containers, details of which could then be set out in regulations.

  Ensuring minimum product and safety standards helping to prevent users from endangering themselves or others – especially children – is sound justification for reference to them in legislative definitions of nicotine delivery.

- The provisions are broadened to include nicotine delivery by smokeless tobacco products, notably Swedish snus.

- Ensuring legislation and regulations do not preclude other emerging tobacco products, notably "heat-not-burn" tobacco products that do not involve combustion and therefore, technically, do not produce smoke.

Airports Act 1996 and vaping in premises under Commonwealth jurisdiction

The intent of the provision is to permit vaping in airports, as being premises under Commonwealth jurisdiction, and not simply to deem vaping as being identical to smoking. This implies the Commonwealth should be a model operator and landlord.

This intent is supported. Airport authorities should be able to determine where vaping, or smokeless tobacco use, may be permitted on their premises, consistent with public norms and occupational health and safety considerations.

This includes designated vaping spaces in airport terminal concourses, gate lounges and other public facilities. Leased spaces, such as private airline lounges and, potentially, vaping cafes as appearing in the United Kingdom, could also be permitted, provided that the absolute ban on tobacco smoking remains in force.

There is particular merit in permitting vaping cafes and lounges to operate in airport precincts.

Vaping cafes and bars are thriving, notably in the UK, and offer vapers a place where they replace the pleasurable social aspects of smoking with venues they can do the same with low-risk vaping. To avoid any annoyance and inconvenience to non-users, such premises could be sealed from surrounding environments, as smoking lounges are in many overseas airports currently are.

Civil Aviation Regulations

Furthermore, the *Civil Aviation Regulations 1988* currently do not refer to vaping, although in practice strict bans are applied as for smoking.

If the intent of this Bill is to make consequential amendments to Acts, it could be broadened to allow the Minister for Transport to make regulations under the *Civil Aviation Act 1988* to permit airline operators to have the discretion to in turn permit vaping on board Australian-registered passenger aircraft in some instances, such as a designated lounge space on a long-haul aircraft like the A380.

It would then be up to the operators to decide their own policies after consulting with air and cabin crews, and customers.

Vaping in other premises under Commonwealth jurisdiction

Taken further, this Bill could clarify the extent to which vaping is permissible, in what designated indoor and outdoor spaces, and under what circumstances, in premises and facilities under Commonwealth control.

This could include:

- Official Defence establishments.
- Official residences and their precincts, including Government House, The Lodge and Kirribilli House; and
- Parliament House and its precincts, presumably subject to the directions of the Presiding Officers.

If this was permitted, any existing smoking prohibitions would be unaffected in those places.

Tobacco Advertising Prohibition Act 1992

The Bill amends this Act to make advertising of ENDS permissible, as opposed to advertising for tobacco products.

The simple amendment proposed in the Bill, merely clarifying the section 8 definition of smoking to exclude non-combustible products is, however, insufficient.

The current definition of “tobacco products” in section 8 of this Act also needs amending to ensure it not only excludes ENDS, but smokeless products like snus and emerging heat-not-burn tobacco products.

Given this,

The definition of “tobacco product” should be amended by:

- Delating sub-paragraph (a): tobacco (in any form)
- Amending sub-paragraph (b) to specify that it applies only to products as specified in the sub-paragraph <u>if</u> they involve their tobacco content being burned by a combustion process.

Whether or not an additional definition for ENDS and smokeless products is included in this Act is a separate Government policy decision, and could be inserted later if required. My view, however, is this Act is not the appropriate place to regulate advertising of these products.

Nevertheless, the extended amendments to this Act proposed here would allow the possibility of subsequently regulating the marketing and advertising of ENDS and other non-combustible nicotine products, including heat-not-burn products, either under general advertising codes, or under specific codes applying to smoking cessation products such as nicotine gum and patches.

The precise approach would need to be worked out by Commonwealth Health, Communications and Consumer Affairs ministers, in open consultation with parties including state and territory governments, the Advertising Council of Australia, the Australian Competition and Consumer Commission, product manufacturers and consumers and, of course, consumers.

The framework for such an approach could be informed by the House of Representatives inquiry findings and, should this Bill be passed, incorporated by later amendment of the resulting Act.

State and territory legislation and regulation

This Bill does not purport to override any state and territory legislation.

Should it or legislation like it be enacted, however, it is highly likely there would be strong public pressure for state and territory legislation to be amended to reflect it. This particularly relates to provisions broadening legalised access to nicotine delivery other than tobacco prepared and packed for smoking.

As I argued in my submission to the House of Representatives inquiry, there is a real hodge-podge of state and territory regulation around vaping, predominantly deeming ENDS as dangerous as combustible cigarettes, or worse. It is highly desirable that the Commonwealth leads a national agreement a vaping regulatory regime to ensure consistency across Australia. That, however, is a matter of policy separate to the consideration of this Bill.

CONCLUSION

These suggestions are made to the Committee for its consideration. I would be happy to discuss them at a hearing if the Committee desires.

Yours faithfully,

Terry Barnes
Principal, Cormorant Policy Advice
Fellow, Institute of Economic Affairs (UK)

APPENDIX A

About the author – Terry Barnes

I have an extensive background in politics and policy-making as a federal and state government official, and as a senior ministerial adviser to two Australian heath ministers, Michael Wooldridge and Tony Abbott.

My chief expertise is in social policy, particularly health and aged care.

Health policy based on reducing harm has interested me over a long time, and I have worked in developing and implementing policy with a harm reduction emphasis, including narcotic drugs and HIV policy. I have also advocated Private Health Insurance incentives promoting people to take greater personal responsibility for their behavioural choices, especially in relation to smoking, alcohol consumption and improving diet and exercise.

Since 2007 I have run my own practice as a policy and regulatory analyst and consultant. In this capacity, in 2013-15 I was centrally involved in the policy, political and media debate over mandatory co-payments for GP services, after I was commissioned to write a discussion paper for a private health think tank, the Australian Centre for Health Research.

In 2015 was appointed as a part-time fellow in lifestyle economics of the UK Institute for Economic Affairs[1]. As an IEA fellow, I have complete freedom to write and advocate, and this submission represents my personal views, not those of the IEA or any third party.

I also write and comment on harm reduction and ENDS in Australian media and policy circles, but I have never smoked or vaped.

My concern simply is ensuring those who do and want to quit have the widest possible range of alternatives to smoking, and that new harm-reducing innovations are accepted as soon as there is sufficient empirical scientific evidence to justify them.

[1] www.iea.org.uk – Like Australian think tanks, the IEA is an independent organisation that receives donations from a wide range of private sector sources and philanthropy.